

## REMARKS

### I. Applicants' Invention and Preliminary Comments.

This is in response to the Decision on Appeal in which the Board affirmed various rejections, vacated another and entered a new rejection. Applicants respond by amending the claims to specify that the microbial preparation is Bifidobacterium and to further require that the microbes are not spores. The amendment to recite Bifidobacterium is supported throughout the specification such as at page 5, line 9 and it is further noted that Bifidobacteria are not spore-formers (See Appendix A attached hereto).

Applicants' invention relates to the discovery that harvested bacteria which have been previously cultured in or grown on resistant starch and then subsequently incorporated into a product have improved viability and survival/recovery rates (compared with the same bacteria cultured in or grown on a medium not containing resistant starch). Thus, for example, Bifidobacteria grown on media containing resistant starch has a superior survival/recovery rate compared to the same strain of Bifidobacteria grown on media which does not contain resistant starch.

It is hypothesized that these improvements in the harvested bacteria are due to some biochemical change in the microbes themselves. However, as no conventional structural limitation to the microbes themselves can be added to the claims, the microbes can only be defined by the process steps by which they are made. Thus, Applicants have defined the microbes using process limitations which define how the novel microbes are produced. These process steps impart distinctive structural characteristics to the final microbes that manifest themselves in an improved survival/recovery rate.

### II. Outstanding Rejections

The rejection of claims 41, 76-77, 79, 81, 88, 90-105, 109-120, 124-135 and 139-150 under 35 U.S.C. § 102(b) as being anticipated by Masuda, U.S. Patent 5,143,845 was affirmed by the Board.

The rejection of claims 41 and 76-153 under 35 U.S.C. § 102(b) as being anticipated by Brown et al., U.S. Patent 6,060,050 in light of evidence by McNaught et al., U.S. Patent

5,714,600 was said to be affirmed by the Board (see page 2 of the Decision on Appeal) but appears to have been vacated at pages 11 and 12 of the Decision.

The previous rejection of claims 41 and 76-153 under 35 U.S.C. § 103(a) as being unpatentable over Masuda taken with Brown et al. and McNaught et al. was said to be vacated by the Board (see page 2 of the Decision on Appeal) although it appears to be maintained at pages 12-16 of the Decision.

The rejection of claims 41 and 76-153 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of Brown et al., U.S. Patent 6,221,350 was affirmed by the Board.

The Board entered a new ground of rejection in which Masuda was said to disclose the step of "harvesting the cultured microbes" in claim 41.

### **III. Patentability Arguments**

#### **A. The Rejection of Claims 77, 79, 81, 88, 90-105, 109-120, 124-135 and 139-150 Under 35 U.S.C. §102(b) over Masuda et al. U.S. 5,143,845 Should be Withdrawn.**

The rejection of claims 77, 79, 81, 90-105, 109-120, 124-135 and 139-150 under 35 U.S.C. § 102(b) as being anticipated by Masuda, et al. (US 5,143,845) should be withdrawn in light of the amendments to the claims specifying that the microbial species are Bifidobacteria species. Such species, by definition, are non-spore formers (See Appendix A) and thus avoid anticipation by Masuda.

Product-by-process claims are limited only by the final structure of the product obtained and the patentability of a product does not depend upon its method of production. Applicants' claims are drawn to the microbial preparations themselves and those harvested microbes are different from those of the prior art.

Thus, the present invention pertains to microbes which are cultured on and harvested from resistant starch-based media. It has been discovered that such microbes are superior to those grown on other media in that they have improved survival/recovery rates. Thus, for example, Bifidobacteria grown on media containing resistant starch has a superior survival/recovery rate compared to the same strain of Bifidobacteria grown on media which does not contain resistant starch.

There is no evidence in Masuda which would indicate otherwise. The Examiner states that the microbes “effectively proliferate” and “demonstrate satisfactory effects upon administration.” However, neither of these show that the microbes have improved survival/recovery. While the microbes in Masuda are “characterized by heat stability, dry stability and drug stability” this is “after spore formation” which is excluded by the claims as amended.

Moreover, Applicants have narrowed their claims to recite Bifidobacteria for which their data support improved survival and recovery. While the Board acknowledged that the evidence regarding Bifidobacterium strain C rebutted the prima facie rejection, Applicants submit that their data support the broader genus of all Bifidobacterium strains and thus rebut the prima facie rejection with respect to that genus.

Therefore, the present invention is novel over Masuda and the rejections of claims 77, 79, 81, 90-95, 96, 97, 100-105, 109, 110, 115-120, 124, 125, 130-135, 140, 141 and 145-150 over Masuda should be withdrawn. Moreover, claims 102, 103, 117, 118, 120, 132, 133, 135, 147, 148 and 150 are further novel in that Masuda does not teach incorporating the microbes into the listed products.

**B. The Rejection of Claims 77-153 Under 35 U.S.C. §102(b) Over Brown et al. In View of McNaught et al. Should Not be Reentered.**

The rejection of claims 77-153 under 35 U.S.C. § 102(b) as being anticipated by Brown, et al. (US 6,060,050) in the light of evidence by McNaught, et al. (US 5,714,600) appears to have been vacated on the basis that Brown ‘050 does not qualify as prior art against the present application under 35 U.S.C. §102(b). Nevertheless, the rejection should not be reentered under any other sub-section of Section 102 withdrawn because Brown ‘050 neither harvests microbes grown on resistant starch nor puts such microbes into products.

First, Brown neither harvests the microbes nor puts them into products. Brown grows fecal bacteria to count them. As one skilled in the art knows, harvesting microbes typically involves separating them from the media. This not only concentrates the microbes, but also typically removes by-products of the proliferation (e.g. fermentation). In contrast, counting or enumerating bacteria involves removing a small aliquot of bacteria with its environment (in the case of Brown, with fecal material) and allowing it to proliferate to count. For

example, by spreading on agar, each microbe develops a colony such that one can count the bacteria in the original fecal sample.

Second, Brown neither provides any comparative experiment on a conventional substrate such as glucose nor identifies the improved survival/recovery of bacteria grown and harvested from resistant starch substrates. In contrast, the present invention shows improved survival/recovery rates of microbes grown on resistant starch. Further, as can be seen in the figures of Brown, the microbes have a lag time before they start to grow. In contrast, the presently claimed microbes do not display such lag time. For example, see figures 9A and 9B of the Brown reference and compare to Figure 1 of the present invention. This lag time is also shown in the present invention for microbes cultured on glucose in Figure 1. Thus, it is clear that the microbes cultured on resistant starch are different from those cultured on other media, such as glucose and the rejection has been overcome.

With respect to claims 78, 80, 82-87, 89-93, 106-108, 121-123, and 136-138, the claims further differ from the disclosure of Brown '050 in that there is no disclosure or suggestion in Brown that the microbes grown on resistant starch and harvested there from may be used in a microbial preparation containing resistant starch.

With respect to claims 94, 109, 124, and 139, the claims further differ from the disclosure of Brown '050 in that there is no disclosure or suggestion in Brown that the microbes are substantially resistant to stresses.

With respect to claims 100-108, 115-123, 131-138, and 146-150, the claims further differ in that there is no disclosure or suggestion in Brown that the microbes cultured on resistant starch may then be added to a product. Accordingly, the rejection of claims 77-153 over Brown '050 should be withdrawn.

**C. The Rejection Under 35 U.S.C. §103(a) over Masuda, Brown et al. and McNaught et al. Should be Withdrawn.**

The rejection of claims 77-153 under 35 U.S.C. § 103(a) as being unpatentable over Masuda, et al. (US 5,143,845) taken with Brown I, et al. (US 6,060,050), Brown II, et al. (High amylose maize starch as a versatile prebiotic for use with probiotic bacteria, "Food Australia 50(12), December 1998, and McNaught, et al. (US 5,714,600) should be withdrawn in light of the amendment of the claims to recite that the microbes are Bifidobacterium species and not in the form of spores. The Board agrees that the improved survival and

recovery data support the rebuttal of a prima facie case against Bifidobacterium strain C and Applicants submit that those of skill in the art would recognize, based on the data in the specification, that other Bifidobacterium strains would be characterized by similar improved properties.

While McNaught is relied upon by the Examiner to demonstrate that certain resistant starches are available in the prior art, it does not cure the remaining deficiencies mentioned above, particularly that microbes cultured on resistant starch and harvested there from have improved survival/recovery. For these reasons, the rejections of claims 77-153 should be withdrawn.

**D. The Rejection Under the Judicially Created Doctrine of Obvious-Type Double Patenting Over Brown et al. Should be Withdrawn.**

Finally, the obviousness-type double patenting rejection of claims 77-153 over claims 1-12 of U.S. Patent No. 6,221,350 ("Brown III") should also be withdrawn because the microbes of Brown III do not have the improved survival/recovery properties of the claimed microbes. This is because the Brown III microbes are cultured on media which do not contain resistant starch. While the microbes belong to the same species and are able to use resistant starch as a nutritional source they are not the same. Moreover, the capability of using resistant starch as a nutritional source and having been cultured on it clearly differ. Further, there is no disclosure in Brown III that the microbes are harvested.

The double patenting rejection also reflects a misunderstanding of the difference between the invention and of probiotic compositions. The probiotic compositions of Brown III comprise the combination of microbes and resistant starch but are not necessarily microbes which are the products of culturing on a resistant starch containing media (which resistant starch might have been consumed by the microbes and may no longer be present.)

The Board held that Applicants' showing of unexpected results for Bifidobacterium strain C rebutted any prima facie obviousness over Brown III. Applicants submit that their showing supports claims to Bifidobacteria generally and that accordingly the obviousness type double patenting rejection should be withdrawn and each of claims 77-153 should be allowed.

### CONCLUSION

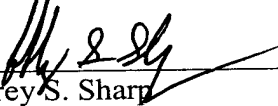
For all of the foregoing reasons, the Applicants respectfully request that the rejections should now be withdrawn and an early notice of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 13-2855. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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**APPENDIX A**  
PDR Health.com  
Probiotics